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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,014	03/01/2002	Henrik Hansen	12013/59301	2646
23838	7590	07/14/2004	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			MICHENER, JENNIFER KOLB	
		ART UNIT	PAPER NUMBER	
			1762	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<i>Supplemental Office Action Summary</i>	Application No.	Applicant(s)	<i>J. N.</i>
	10/087,014	HANSEN ET AL.	
	Examiner	Art Unit	
	Jennifer K. Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 February 2004.
- 2a) This action is **FINAL**, *supplemental*  This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 and 18-29 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 and 29 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-16, 28-29, 25-28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

### **SUPPLEMENTAL DETAILED ACTION**

This final rejection is supplemental to and replaces that of April 30, 2004 due to Examiner's inadvertent omission of newly-added claim 29 in the final rejection.

#### ***Election/Restrictions***

1. Applicant's election without traverse of Group I is acknowledged.

*The following new restriction requirement is made based on Applicant's submission of new claim 29:*

2. This application contains claims directed to the following patentably distinct species of the claimed invention: spraying a therapeutic agent into a rotating drum to coat the medical devices therein and tumbling the medical devices into a vat of therapeutic agent. Spraying and immersion are distinct species of the claimed invention.

Currently, claim 1 is generic.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Newly submitted claim 29 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: this immersion species is distinct from the spraying species previously examined, as outlined above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 29 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

5. The rejection of claims 14 and 15 under 35 U.S.C. 112, second paragraph, has been withdrawn based on Applicant's clarification.

***Claim Rejections - 35 USC § 102***

6. The rejection of claims 1-4 and 25-28 under 35 U.S.C. 102(e) as being anticipated by Schwarz et al. (US 6,368,658 B1) has been withdrawn, as necessitated by Applicant's amendment.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-16, 18-19, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwarz et al. (6,607,598) in view of Forster (4,581,242).

The rejection of claims 5-16 and 18-19 has been maintained.

The rejection of claim 17 has been withdrawn as necessitated by Applicant's cancellation of the claim.

Claims 1-4 and 25-28 have been added to this rejection, as necessitated by Applicant's amendment, for the same reasons as this rejection is applied to claims 5-16 and 18-19.

*Examiner addresses only the newly-added limitations within the claims herein:*

Because the active rotation limitation was added to claim 1, Examiner has included this claim, and those depending therefrom, in this rejection. Schwarz '598 teaches substantially the same method as Schwarz '658, as originally applied as a 102, and is

combined with Forster for the same reasons as applied to claims 5-16 and 18-19, namely that Schwarz '598 teaches drum coating and pan-coating of medical implants and Forster provides the specifics of such an operation.

Claims 5 and 25 now require rotation "about an axis" in a drum with a "plurality of orifices in the wall". Forster teaches rotation about an axis (see Figures) and a drum made of wire mesh, which qualifies as "orifices" (see Figure 4; col. 3, line 2).

Claims 7, 9, 12, 13, 19, now independent and including all the limitations of their previous parent claim, are rejected for the same reasons as provided in the previous office action.

Claim 6 is rejected for those reasons applied to claim 19 and additionally because collection of any fluid inherently requires a reservoir.

#### ***Response to Arguments***

9. Applicant's arguments filed 2/2004 have been fully considered but they are not persuasive.

Applicant argues that the cited references do not disclose a drum with orifices in the wall.

Examiner disagrees for those reasons disclosed above, namely, that the drum, including the walls, of Forster may be made of wire mesh, the holes between the wires meeting the limitation of "orifices". See Figure 4 and col. 3, line 2.

Applicant argues that the processing temperature of Schwarz applies only to the temperature *when* coating, not *after* coating, so that the limitation of "heating... after spraying" has not been met.

Examiner disagrees.

Examiner believes that the quotation provided by Applicant has been taken slightly out of context. Applicant argues that Schwarz teaches only controlling temperature "*when coating with drugs or polymers*" (emphasis added), however, this excerpt, in full, states that temperature is controlled "*when coating with drugs or polymers that degrade... upon exposure to specific environments.... Thus, operating temperatures in at least some embodiments ...are... between 0° C.-200° C.... Thus operating temperatures compatible with all of the coatings materials disclosed herein can be established and maintained in the apparatuses and methods of the present invention.*" Therefore, Schwarz is clearly not teaching that temperature is regulated only during spraying, but rather that temperature is regulated during the entire coating operation when using drugs or polymers which degrade, as evidenced by the fact that Schwarz teaches "*maintaining*" the temperature, as outlined in the previous office action.

Additionally, for example only, see Example 1. In this case, Schwarz teaches coating and then maintaining the heated air flow, after coating has been stopped, until the

stents are dry, therefore this reference teaches heating that continues after spraying, as required by Applicant.

Applicant argues that since the references are silent regarding recycling, that it is erroneous for Examiner to assert that it would have been obvious to recycle therapeutic agent that did not adhere to the implant during spraying.

Examiner disagrees and maintains her argument that it would have been obvious to an ordinary artisan to recycle expensive pharmaceuticals lost in a spray-coating operation. Recycling of high-value coating materials would have been immediately envisioned by one of ordinary skill in the art. Additionally, the use of fume hoods and negative pressure spray-coating booths is well-known in the art of spraying for capturing lost materials. However, Applicant requested Examiner to cite a prior art reference regarding recycling and she does so herein. Mehta (6,627,246) is cited for teaching that spray-coating is known in the art to be problematic, especially when using costly pharmaceutical agents as coatings, because the overspray creates "lost" materials (col. 1, lines 53-56). Examiner cites Hossainy (6,555,157) for teaching spray-coating stents with a composition including a therapeutic agent and recycling the coating material to reduce waste and cost because the recycled materials can be recovered for use in coating other stents (col. 3, lines 38-45; col. 5, line 44; claims).

***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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July 12, 2004